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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,021	01/30/2006	Yukoh Sakata	19331-002US1 OSP-18070	7382
26161	7590	03/18/2008	EXAMINER	
FISH & RICHARDSON PC P.O. BOX 1022 MINNEAPOLIS, MN 55440-1022			SASAN, ARADHANA	
			ART UNIT	PAPER NUMBER
			1615	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/539,021	SAKATA ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ARADHANA SASAN	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 15 June 2005.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-20 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-20 is/are rejected.  
 7) Claim(s) 20 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1.) Certified copies of the priority documents have been received.  
 2.) Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3.) Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____ .
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>6/15/05 and 1/30/06</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____ .

## **DETAILED ACTION**

### ***Status of Application***

1. Claims 1-20 are included in the prosecution.

### ***Priority***

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

### ***Information Disclosure Statement***

3. The information disclosure statements (IDS) submitted on 6/15/05 and 1/30/06 are acknowledged. The submissions are in compliance with the provisions of 37 CFR 1.97 and 1.98. Accordingly, the examiner is considering the information disclosure statements.

See attached copy of PTO-1449.

### ***Claim Objections***

4. Claim 20 is objected to because of the following informalities: Claim 20 is missing a period at the end. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 1-9, 14-17 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Kawata et al. (US 3,798,054).

The claimed invention is a light shielding agent comprising a calcium-containing compound. Also claimed is a film forming composition comprising a calcium-containing compound and a film-forming base, where the calcium-containing compound is provided in a light-shielding agent.

Kawata teaches a tablet that is coated by an aqueous sugar solution containing calcium lactate (Abstract). The coated tablets are “characterized by (1) an acceptable disintegration time, (2) freedom from cracks, and substantially stable on prolonged storage that is, resistant to surrounding or environment conditions such as temperature, moisture, and light, the aforesaid characteristics being far superior to conventional sugar-coated tablets” (Col. 2, lines 37-43). Examples 1-4 disclose coating compositions comprising sucrose and calcium lactate (Col. 5, line 55 to Col. 6, line 65). The calculated calcium lactate weight relative to the weight of the film-forming base agent (in this case sucrose) is 15.87% (Example 1), 6.45% (Example 2), 16.43% (Example 3) and 17.21% (Example 4). These weight percentages are within the recited range of 0.1 to 150% by weight of instant claim 14. Kawata teaches that for “applying the coating solution to tablet cores, the coated solution heated ordinarily to about 60°C was sprayed onto the tablet cores ...” (Col. 5, lines 42-45).

Therefore, all the limitations of claims 1-9 and 14-17 are anticipated by the teachings of Kawata.

7. Claims 1-3, 5-13 and 15-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Iwata et al. (WO 01/40182 A2).

Iwata teaches a solid preparation that may be "tablets, capsules, granules ..." (Page 22, lines 14-17). Iwata teaches polymeric film coating of the tablets where the polymeric ingredient may be "hydroxypropylmethylcellulose, hydroxypropylcellulose, hydroxyethylcellulose, methylhydroxyethyl-cellulose" (Page 24, lines 5-11). Several non cellulose base polymers (including carmellose sodium, polyvinylpyrrolidone, polyvinyl alcohol, polyethylene glycol, dimethyl-aminoethyl methacrylate-methyl acrylate copolymer, and ethyl acrylate-methyl methacrylate copolymer) are also disclosed as the film forming polymers for the solid preparation (Page 24, lines 5-14). Iwata also teaches that "in order to protect from light or to improve the discriminability, a suitable coloring agent may be added into a coating agent. The coloring agent may be ... calcium sulfate, calcium carbonate ..." (Page 24, lines 19-24). Iwata also discloses the use of pullulan as a further component of the coating composition (Page 25, lines 2-6).

Therefore, all the limitations of claims 1-3, 5-13 and 15-20 are anticipated by the teachings of Iwata.

### ***Conclusion***

8. No claims are allowed.
9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aradhana Sasan whose telephone number is (571) 272-9022. The examiner can normally be reached Monday to Thursday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, can be reached at 571-272-8373. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Aradhana Sasan/  
Examiner, Art Unit 1615

/Michael P Woodward/  
Supervisory Patent Examiner, Art Unit  
1615